

**UNITED STATES DISTRICT COURT
FOR THE NORTHER DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

Track Three Cases

**MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster**

**CERTAIN DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR
DAUBERT MOTION TO EXCLUDE
THE OPINIONS OFFERED BY JAMES RAFALSKI**

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I. INTRODUCTION

Defendants Giant Eagle, Inc. and HBC Service Company, Rite Aid,¹ and Walmart Inc. (“Moving Defendants”) move to exclude the opinions of James Rafalski. As in CT1, Plaintiffs in CT3 retained Rafalski, a former DEA Diversion Investigator, to opine that the CT3 Pharmacy Defendants failed to “to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market,” and further that “this systematic failure was a substantial cause of the opioid epidemic plaguing the country and specifically in Lake County and Trumbull County.” Ex. 1 (“Rep.”) at 7. This Court previously excluded Mr. Rafalski’s legal opinions regarding whether Defendants complied with the DEA’s security regulations, but Mr. Rafalski’s report did not address the Moving Defendants in CT1. While it does now, it is once again filled with legal opinions regarding the requirements of the CSA, and whether the Moving Defendants violated the governing DEA regulations. See Rep. at 8-9 (summary of opinions). As it did in CT1, the Court should exclude these legal opinions as to the Moving Defendants. See Doc. 2494 (the “CT1 Order”) at *8 (“[T]o the extent Rafalski expresses opinions as to what the law requires, or whether the Defendants’ conduct violated the law, his opinions are not admissible.”).

Rafalski’s opinions should also be excluded as to Moving Defendants because he did not use the reliable methodologies regularly relied upon by CSA regulatory compliance experts in formulating their opinions and instead devised new untested methods solely for this litigation. The Supreme Court has made clear that experts must “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Yet, Rafalski did not use the same methods to

¹ Rite Aid Hdqtrs. Corp., Rite Aid of Ohio, Inc., Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center and Eckerd Corp. d/b/a Rite Aid Liverpool Distribution Center.

reach his conclusions about Moving Defendants that he used when he was a DEA Diversion Investigator, nor indeed a method used by *any* DEA Investigator.

As the Sixth Circuit has made clear, an expert cannot devise a method solely for the purposes of supporting a party in litigation, unless the party proposing the expert can supply the trial court with objective proof that the expert's methods are reliable for their intended purpose. *See Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 434-35 (6th Cir. 2007). Plaintiffs have provided no objective proof that the methods Rafalski used for this litigation were reliable as to Moving Defendants.

And in fact, Rafalski provides no explanation at all for why more experienced DEA Investigators, using the actual methods used by DEA Investigators in the field, repeatedly approved and renewed Moving Defendants' licenses. This unexplained discrepancy alone shows the unreliability of his methods in this litigation.

Rafalski's *ipse dixit* causation opinions about Moving Defendants, based on his created-for-litigation "seven methodologies" analysis, are equally unreliable and unhelpful. Rafalski admitted that companies like Moving Defendants, who only distributed opioids to their own pharmacies, could only have contributed to the opioid crisis if their pharmacies were dispensing opioids that were diverted. But Rafalski did not even consider diversion at the pharmacy level before reaching his conclusion that Moving Defendants helped cause the opioid crisis in Lake and Trumbull Counties.

Rafalski also acknowledges that other actors contributed greatly to the opioid crisis. But once again, Rafalski did not analyze these confounding causes. Why? Because he was not instructed to do so. Ex. 2 ("Tr.") at 107-08. Rafalski's "[was] not asked to consider" excuse is really no excuse at all for failing to consider known confounding factors when rendering a

causation opinion, and such an opinion should be excluded as unreliable and unhelpful. *See Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 253-54 (6th Cir. 2001).

In fact, the only objective evidence proves the unreliability of his methods. For example, some of the methodologies he uses flag zero of Moving Defendants' orders as suspicious, while others flag all of Moving Defendants' orders. If the *Daubert* test for reliability means anything, it must mean that an expert cannot offer a smorgasbord of newly-devised and untested methodologies with an astronomical error rate to the jury, particularly where some of the results reached when applying those methodologies to the case are fundamentally inconsistent with the expert's overall opinions.

In light of these fatal flaws, Rafalski's testimony regarding Moving Defendants' SOM systems, causation, and other technical issues involving diversion will not be helpful to the jury in this case. It is not surprising that Rafalski's made-for-litigation analysis conflicts with the audit reports that Moving Defendants received from their actual regulatory inspectors. By failing to employ the methods he used as a working professional, or at least a method with objective indicia of reliability, Rafalski flunks the tests articulated by the Supreme Court and the Sixth Circuit. Accordingly, the Court should exclude (1) Rafalski's legal opinions and conclusions regarding Moving Defendants' purported noncompliance with the DEA's security regulations; (2) his opinions about the effectiveness of Moving Defendants' SOM systems; and (3) his opinions about the role Moving Defendants played in causing the diversion of opioids in Lake and Trumbull Counties.

II. BACKGROUND

A. Rafalski's Legal Opinions and Ultimate Conclusions

Despite the Court's CT1 Order, Rafalski again devotes the bulk of his report to legal opinions about the CSA and DEA regulations, and then conclusions about whether the CT3

Defendants, including Moving Defendants, complied with his understanding of what registrants were required to do. Rafalski's legal conclusions about Moving Defendants are as inadmissible as they were in CT1.

B. Rafalski's Unreliable Methods for Analyzing Moving Defendants' Security Systems

When deposed in CT3, Rafalski admitted that compliance with the overarching security regulation (Section 1301.71) is determined by "substantial compliance" with Sections 1301.72-76—which includes the SOM regulation, but only among many others. Rafalski acknowledged that the DEA security regulations do not require "perfect compliance." Tr. 87-90. And while each DEA inspection includes a review of the SOM system, a registrant's compliance with the SOM regulation is not "more important" than compliance with any other security regulation. Tr. 459-460.

As to SOM systems, Rafalski admitted that analysis of a SOM system needs to take into consideration the nature of each registrant's business and any other unique factors. Tr. 112. Rafalski concedes that the DEA regulations do not specify any particular methodologies—nor do they even require that the system rely on automated, rather than manual, identification of suspicious orders. Tr. 113. In fact, as a DEA Diversion Investigator, Rafalski personally found that a distributor with a manual SOM system was in full compliance. Tr. 451-452, 486. Distinguishing companies like the Moving Defendants from the typical third-party distributor, Rafalski acknowledges that corporate-owned chain pharmacies are "well aware of what their pharmacies are purchasing." Tr. 254.

Ignoring his own practice and advice when he was a DEA Diversion Investigator, Rafalski never physically inspected Moving Defendants' distribution facilities, even though such an inspection would be "important." Tr. 440. Rafalski did not investigate or even consider the

controls that Moving Defendants had in place at the pharmacy level. He did not account for the fact that the Moving Defendants' controls/non-controls ratio in Lake and Trumbull Counties—a standard metric used by the DEA to identify possible diversion—was well within the range identified by DEA as reasonable. In short, despite being offered as an expert witness based entirely on his experience as a DEA Diversion Investigator, Rafalski did not do anything close to what he admitted DEA Diversion Investigators are trained to do, and would have done, to investigate Moving Defendants with respect to the issues on which he opines.

Rafalski did not even review Moving Defendants' DEA inspection reports, even though a review of these reports would be "important." Tr. 454-455, 461-462.² In fact, Rafalski admitted that registrants are entitled to rely on their favorable inspection reports, which are prepared by trained and experienced DEA Investigators who conduct on-site investigations of the registrants' operations and SOM systems. Tr. 81-82. Indeed, according to Rafalski, his practice as required by the DEA was to include the results of past DEA inspections in the beginning of each inspection report. Tr. 468-469. But he ignored them for the purposes of providing his opinions about Moving Defendants in this litigation.

Finally, Rafalski could not explain why he only found about 50 percent of distributors to have noncompliant SOM systems when he was a DEA Diversion Investigator, but, as a paid expert for Plaintiffs, he found 100 percent of SOM systems he has examined to suffer from "systemic" violations of the DEA's security regulations. Tr. 46-47, 85-86. This unexplained difference is an objective indication of how much his methods as an expert witness departed from the methods he used at the DEA.

² Similarly, Rafalski did not even review the testimony of the Ohio Board of Pharmacy agents who actually did inspect the Moving Defendants' facilities and found them to be in compliance. Tr. at 158-160.

C. Rafalski's Unreliable and Unhelpful Causation Opinions

In support of his causation opinions about Moving Defendants, Rafalski reviewed seven methodologies he opined could potentially be used to identify suspicious orders. See Rep. at 45.

After reviewing the methodologies in purported application to Moving Defendants, he opined:

Based on my education, background, and experience, as well as my review of relevant documents, the absence of adequate distributor due diligence and failure to respond to indicators of suspicious orders as described in this report constitutes the Defendants' failures to comply with the requirements of the Controlled Substances Act. It is further my opinion that this misconduct led to the excess quantity of opiate pills flooding the illicit market in CT3 jurisdictions.

Rep. at 57.

Again, the first part of this opinion is an inadmissible legal conclusion. The second part is a causation opinion, which is pure speculation as applied to Moving Defendants.

Rafalski acknowledged that companies like Moving Defendants only distributed opioids to their own pharmacies. Tr. 26. Because they are self-distributors, Rafalski also admitted that such entities cannot have caused damage to Plaintiffs even if they have noncompliant SOM systems, unless substantial diversion occurs at their pharmacies due to poor controls. Tr. 109-110, 111-112. To determine whether a pharmacy is likely or unlikely engaged in diversion, Rafalski admitted that standard practice for the DEA (which he followed when with the DEA) was to look at the cash payment percentage, total prescription dispensing volume, geographic location, and ratio of controls to non-controls. Tr. 123-24. Outside of the context of this litigation, Rafalski also advised physically going to pharmacies to look for long lines in the parking lot and out of state license plates, as indications of diversion. Tr. 145. But Rafalski explained that he did not conduct "[any] analysis or do any research or review any records to formulate an opinion related at a pharmacy level," because he "was not asked to do that." Tr. at 45-46.

Rafalski also admitted to not considering any possible confounding factors, again on the excuse that he was not asked to by Plaintiffs. Tr. 107-108. He did not consider the possible contributions of entities such as the other distributors, manufacturers, independent pharmacies, or bad doctors. Tr. 107-109. He admitted that bad doctors contributed “significantly” to the opioid crisis, but he did not analyze their contribution in Lake and Trumbull Counties. Tr. 208. He admitted he did not consider internet pharmacies. Tr. 408. He admitted he knew while he was with the DEA that Detroit drug gangs were a major supplier of drugs to neighboring states, including Ohio, Tr. 409-410, but now as an expert witness he admitted he did not consider the supply of opioids to Lake and Trumbull Counties by Detroit drug gangs. Tr. 411.

Having not conducted any such causation analysis, Rafalski admitted he could not in any way quantify the purported contribution of the CT3 Defendants, including Moving Defendants, to the opioid crisis in Lake and Trumbull Counties. Tr. at 175-176.

III. THE COURT SHOULD REAPPLY ITS HOLDINGS FROM CT1

To avoid needless repetition, Moving Defendants incorporate by reference the arguments presented by the CT1 Defendants in their motion to exclude Rafalski, Doc. 1900. While exercising its gate-keeping function, the Court partially granted that motion by refusing to allow Rafalski to offer an opinion on the ultimate legal issues. CT1 Order at *8 (“[T]o the extent Rafalski expresses opinions as to what the law requires, or whether the Defendants’ conduct violated the law, his opinions are not admissible.”).

Nevertheless, throughout his CT3 report, Rafalski opined on what the CSA and related security regulations required the CT3 Defendants to do as distributors, and then how he believed Moving Defendants violated these laws and regulations. All of these opinions should again be excluded as to Moving Defendants for the same reasons the Court held in CT1.

IV. RAFALSKI'S MOVING DEFENDANTS' SOM SYSTEM OPINIONS IN CT3 ARE NOT BASED ON A RELIABLE METHOD

Based on Rafalski's "experience and expertise regarding components and characteristics he would expect to be included in an effective SOMS . . . ," the Court left him a narrow opening in CT1 to "express opinions as to particular characteristics in SOMS and due diligence procedures that he finds are effective in preventing diversion." *Id.* at 8, 9. New evidence obtained in CT3 discovery requires this Court to now close that opening as to Moving Defendants.

That new evidence principally includes detailed inspection reports of Moving Defendants' SOM systems and overall controls against diversion prepared by Rafalski's former DEA colleagues. Those reports indicate, for instance, that Giant Eagle was in full compliance with the security regulations and that each DEA Diversion Investigator took into consideration the fact that Giant Eagle only distributes to its own pharmacies when analyzing the effectiveness of its SOM systems and other diversion controls. *See* Ex. 3 (Colosimo Ex. 3).

In his deposition, Rafalski admitted that he did not bother to review any of Moving Defendants' inspection reports, nor analyze why those experienced DEA inspectors reached such different opinions from the ones about Moving Defendants that he plans to offer on behalf of Plaintiffs. Nor did he give any consideration to the fact that each Moving Defendant only distributes to itself. These admissions render Rafalski's opinions on the effectiveness of Moving Defendants' SOM systems inherently unreliable.

A. The *Kumho Tire* Standard for Professional Experience Experts

In expanding its *Daubert* holding to non-scientific experts, the Supreme Court held that "Federal Rules 702 and 703 grant expert witnesses testimonial latitude unavailable to other witnesses on the 'assumption that the expert's opinion will have a reliable basis in the knowledge

and experience of his discipline.”” *Kumho Tire*, 526 U.S. at 148 (quoting *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 592 (1993)). For this reason, “the trial judge must determine whether the testimony has ‘a reliable basis in the knowledge and experience of [the relevant] discipline.’” *Id.* at 149 (quoting *Daubert*, 509 U.S. at 592). “The objective of that requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Id.* at 152.

B. Rafalski Admitted Disregarding the Methodologies Always Used by The DEA When He Became an Expert Witness for Plaintiffs in CT3

1. Rafalski’s Cursory Investigation

For the purposes of forming his opinions about Moving Defendants, Rafalski did not consider any of the factors he would have as a DEA Diversion Investigator. Tr. 124. Nor did he do the type of physical investigation of Moving Defendants’ pharmacies that he recommended to identify possible diversion. Tr. 239. And despite their wealth of information regarding diversion, Rafalski did not review the testimony from the three Ohio BOP agents who actually inspected and investigated Moving Defendants’ pharmacies in Lake and Trumbull Counties. Tr. 156, 159. As a result, Rafalski admitted that he has no clue how much diversion if any occurred at any of the pharmacies operated by Moving Defendants in Lake and Trumbull Counties. *See* Tr. 209-210.

2. Rafalski Failed to Follow His Own Practice and Advice to Determine Moving Defendants’ Compliance with The DEA’s Distributor Regulations

Put simply, Rafalski did not use the same established and reliable methodologies and tools to investigate Moving Defendants that he used as a DEA Diversion Investigator. As such, Rafalski relied on methodologies “solely for the purposes of litigation” that have nothing to do

with his qualifying professional experience as a DEA Diversion Investigator. Rafalski's failure to draw on his qualifying experience and to use tried and true methods for determining Moving Defendants' compliance with DEA security regulations renders his opinions unreliable and thus inadmissible. *See Johnson*, 484 F.3d at 434-35; *see also Mike's Train House, Inc. v. Lionel, L.L.C.*, 472 F.3d 398, 408 (6th Cir. 2006). As the Sixth Circuit explained in *Johnson*:

If it is clear that a proposed expert's testimony flows naturally from his own current or prior research (or field work), then it may be appropriate for a trial judge to apply the *Daubert* factors in somewhat more lenient fashion. This would not mean that such an expert is to be accorded a presumption of reliability, but it would be in line with the notion that an expert who testifies based on research he has conducted independent of the litigation provides important, objective proof that the research comports with the dictates of good science. However, if a proposed expert is a "quintessential expert for hire," then it seems well within a trial judge's discretion to apply the *Daubert* factors with greater rigor. . . . Such an expert is not [to] be accorded a presumption of *unreliability*, but the party proffering the expert must show some objective proof . . . supporting the reliability of the expert's testimony.

484 F.3d at 435 (citation omitted). It is not enough for admissibility purposes that Rafalski had relevant experience as a DEA Diversion Investigator, as he is not actually using the methodologies learned during that experience in reaching his opinions about Moving Defendants. Nor can Plaintiffs supply the "objective proof" required by *Johnson* to support the reliability of Rafalski's testimony about Moving Defendants, because the Plaintiffs have no evidence that Moving Defendants' SOM systems led to any actual diversion. To the contrary, the available proof of whether Moving Defendants' SOM systems complied with the DEA security regulations establishes that the Moving Defendants were in compliance.

This is precisely the sort of "expert for hire" testimony that a trial court should exclude as unreliable for the reasons stated by the Sixth Circuit in *Johnson*. Rafalski could have drawn on his professional experience to assess Moving Defendants' security measures, including their SOM systems, but he did not. Having failed to apply his own professional experience, and in the

absence of objective proof that his new made-for-litigation methodology is reliable, the Court should exclude his opinions that Moving Defendants' SOM systems were ineffective at preventing diversion.

V. RAFALSKI'S CAUSATION OPINIONS ARE NOT RELIABLE AND WOULD NOT BE HELPFUL TO THE CT3 JURY

A. The Sixth Circuit's Helpfulness Standard

"Rule 702 requires that the testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue.'" *Nelson*, 243 F.3d at 250 (quoting F.R.E. 702). In *Nelson*, an expert sought to opine that the plaintiffs were injured as a result of exposure to chemicals allegedly released into the environment by defendants. *Id.* at 247, 252. The Sixth Circuit upheld the exclusion of this opinion on methodological grounds, because the expert did not evaluate whether the plaintiffs were actually exposed to the defendants' chemicals and, if so, the degree of that exposure. *Id.* at 252-53. Instead, the expert concluded that once the relevant neurological and pulmonary abnormalities suffered by plaintiffs reached a certain level they were, in his view, more likely than not caused by defendants' chemicals. *Id.* at 253.

The expert in *Nelson* admitted his tests "could not identify what caused the impairments, and there were a number of other possible causes or confounding factors." *Id.* The Sixth Circuit then agreed with the trial court that there was no basis for the expert's assumption that the defendants' chemicals, rather than other possible factors, caused the plaintiffs' health issues, and on this basis affirmed exclusion of his testimony. *Id.* at 254; *Nelson v. Tenn. Gas Pipeline Co.*, No. 95-1112, 1998 U.S. Dist. LEXIS 22769, at *17 (W.D. Tenn. Aug. 28, 1998) (trial court finding that "[t]he record shows that [expert] has failed to engage in adequate techniques to rule out alternative causes and offers no good explanation for why his opinion is nevertheless reliable in light of the other potential causes of the alleged injuries"); *id.* at *29-30 (holding that "based

on the foregoing, [expert]’s proffered testimony is not grounded on methodology that is scientifically valid, will not assist the trier of fact, and is likely to mislead the jury”); *see also Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010) (holding that if a causation expert does not “reliably rule out rejected causes” the court “must exclude the ultimate conclusion reached”).

B. Rafalski’s Seven-Methodologies-Based Causation Opinions Are Not Reliable as to Moving Defendants and Would Not Be Helpful to the CT3 Jury

As self-distributors, Moving Defendants are positioned to evaluate whether orders are suspicious with information not available to other sorts of distributors. For example, Rafalski admitted that an increase in controlled substance scripts from a pharmacy would not be unexpected if a company like Moving Defendants knew a competitor pharmacy was closing. Tr. 96-97.

Rafalski in fact further admitted in his CT3 deposition that a registrant did not have to use one of his seven methodologies to comply with the SOM regulation. Tr. 319. Again, he admitted that a manual system could also comply with the SOM regulation. Tr. 326-27.

Rafalski also admitted that his seven methodologies give greatly varying results as applied to Moving Defendants. Tr. 114. He admitted in fact that his methodologies as applied to Moving Defendants ranged from flagging zero percent of orders as suspicious to 100 percent. Tr. 114-115. And he admitted he did not analyze whether any of the “suspicious orders” flagged by his methodologies were ultimately used to fill illegitimate prescriptions. Tr. 431. Again, Rafalski’s made-for-litigation causation methodology is inadmissible due to lack of reliability, as it is neither based on how working professionals would evaluate these issues as applied to Moving Defendants, nor is there any “objective proof” of its reliability and, to the contrary, the random results strongly suggest extreme unreliability.

Rafalski also did not consider possible confounding factors that might actually have caused the opioid crisis in Lake and Trumbull Counties. Having not done such an analysis, he admitted it was impossible for him to quantify in any way to what extent Moving Defendants purportedly contributed to the harms in Lake and Trumbull Counties.

In both those senses, his seven methods opinions as applied to Moving Defendants have the same glaring causation gaps that the trial court and Sixth Circuit in *Nelson* held warranted exclusion. Rafalski's causation opinions are not reliable, and will not be helpful to a jury seeking to determine whether the opioids that Moving Defendants distributed, and that their pharmacists dispensed, were in any way a "substantial cause of the opioid epidemic."

VI. CONCLUSION

The Court should exclude as unreliable and unhelpful to the jury Rafalski's opinions that Moving Defendants failed to "to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market," and further that "this systematic failure was a substantial cause of the opioid epidemic plaguing the country and specifically in Lake County and Trumbull County." It should also exclude Rafalski's opinions on what the law required of Moving Defendants, and whether Moving Defendants complied with those requirements, for the same reasons that it excluded those types of opinions in CT1. But the Court should now also go further and exclude all of Rafalski's opinions purportedly analyzing the effectiveness of Moving Defendants' SOM systems, as he failed to apply his professional expertise as a DEA Diversion Investigator when forming those opinions, and the objective indicia only suggest the unreliability of his opinions as applied to Moving Defendants. The Court should also exclude his causation opinions about Moving Defendants as based on his seven methodologies, as those methodologies are objectively unreliable as applied to the Moving Defendants. His causation opinions also fail

to address known possible confounding factors that could actually have caused the opioid crisis in Lake and Trumbull Counties.

Because none of Rafalski's methods as applied to Moving Defendants were actually based on his professional experience, and because they would be unhelpful to jury as it considers the relevant issues in this case, the Court should grant Moving Defendants' Motion to Exclude.

Dated: July 23, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record on July 23, 2021.

/s/ Scott D. Livingston